

§ 876.1620 Urodynamics measurement system.

(a) *Identification.* A urodynamics measurement system is a device used to measure volume and pressure in the urinary bladder when it is filled through a catheter with carbon dioxide or water. The device controls the supply of carbon dioxide or water and may also record the electrical activity of the muscles associated with urination. The device system may include transducers, electronic signal conditioning and display equipment, a catheter withdrawal device to enable a urethral pressure profile to be obtained, and special catheters for urethral profilometry and electrodes for electromyography. This generic type of device includes the cystometric gas (carbon dioxide) device, the cystometric hydraulic device, and the electrical recording cystometer, but excludes any device that uses air to fill the bladder.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 63 FR 59228, Nov. 3, 1998]

§ 876.1725 Gastrointestinal motility monitoring system.

(a) *Identification.* A gastrointestinal motility monitoring system is a device used to measure peristaltic activity or pressure in the stomach or esophagus by means of a probe with transducers that is introduced through the mouth into the gastrointestinal tract. The device may include signal conditioning, amplifying, and recording equipment. This generic type of device includes the esophageal motility monitor and tube, the gastrointestinal motility (electrical) system, and certain accessories, such as a pressure transducer, amplifier, and external recorder.

(b) *Classification.* Class II (performance standards).

§ 876.1735 Electrogastrography system.

(a) *Identification.* An electrogastrography system (EGG) is a device used to measure gastric myoelectrical activity as an aid in the

diagnosis of gastric motility disorders. The device system includes the external recorder, amplifier, skin electrodes, strip chart, cables, analytical software, and other accessories.

(b) *Classification.* Class II (Special Controls). The special controls are as follows:

(1) The sale, distribution and use of this device are restricted to prescription use in accordance with § 801.109 of this chapter.

(2) The labeling must include specific instructions:

(i) To describe proper patient set-up prior to the start of the test, including the proper placement of electrodes;

(ii) To describe how background data should be gathered and used to eliminate artifact in the data signal;

(iii) To describe the test protocol (including the measurement of baseline data) that may be followed to obtain the EGG signal; and

(iv) To explain how data results may be interpreted.

(3) The device design should ensure that the EGG signal is distinguishable from background noise that may interfere with the true gastric myoelectric signal.

(4) Data should be collected to demonstrate that the device has adequate precision and the EGG signal is reproducible and is interpretable.

[64 FR 51444, Sept. 23, 1999]

§ 876.1800 Urine flow or volume measuring system.

(a) *Identification.* A urine flow or volume measuring system is a device that measures directly or indirectly the volume or flow of urine from a patient, either during the course of normal urination or while the patient is catheterized. The device may include a drip chamber to reduce the risk of retrograde bacterial contamination of the bladder and a transducer and electrical signal conditioning and display equipment. This generic type of device includes the electrical urinometer, mechanical urinometer, nonelectric urinometer, disposable nonelectric urine flow rate measuring device, and uroflowmeter.

(b) *Classification.* (1) Class II (special controls). The device is exempt from the premarket notification procedures

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in subpart E of part 807 of this chapter subject to § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 61 FR 1122, Jan. 16, 1996; 63 FR 59228, Nov. 3, 1998]

Subpart C—Monitoring Devices

§ 876.2040 Enuresis alarm.

(a) *Identification.* An enuresis alarm is a device intended for use in treatment of bedwetting. Through an electrical trigger mechanism, the device sounds an alarm when a small quantity of urine is detected on a sensing pad. This generic type of device includes conditioned response enuresis alarms.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 63 FR 59228, Nov. 3, 1998]

Subpart D—Prosthetic Devices

§ 876.3350 Penile inflatable implant.

(a) *Identification.* A penile inflatable implant is a device that consists of two inflatable cylinders implanted in the penis, connected to a reservoir filled with radiopaque fluid implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum. When the cylinders are inflated, they provide rigidity to the penis. This device is used in the treatment of erectile impotence.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before July 11, 2000, for any penile inflatable implant that was in commercial distribution before May 28, 1976, or that has, on or before July 11, 2000, been found to be substantially equivalent to a penile inflatable implant that was in commercial distribution before May 28, 1976. Any other penile inflatable implant shall have an approved PMA or a declared completed

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PDP in effect before being placed in commercial distribution.

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 65 FR 19658, Apr. 12, 2000]

§ 876.3630 Penile rigidity implant.

(a) *Identification.* A penile rigidity implant is a device that consists of a pair of semi-rigid rods implanted in the corpora cavernosa of the penis to provide rigidity. It is intended to be used in men diagnosed as having erectile dysfunction.

(b) *Classification.* Class II. The special control for this device is the FDA guidance entitled “Guidance for the Content of Premarket Notifications for Penile Rigidity Implants.”

[65 FR 4882, Feb. 2, 2000]

§ 876.3750 Testicular prosthesis.

(a) *Identification.* A testicular prosthesis is an implanted device that consists of a solid or gel-filled silicone rubber prosthesis that is implanted surgically to resemble a testicle.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before July 5, 1995, for any testicular prosthesis that was in commercial distribution before May 28, 1976, or that has on or before July 5, 1995, been found to be substantially equivalent to a testicular prosthesis that was in commercial distribution before May 28, 1976. Any other testicular prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 60 FR 17216, Apr. 5, 1995]

Subpart E—Surgical Devices

§ 876.4020 Fiberoptic light ureteral catheter.

(a) *Identification.* A fiberoptic light ureteral catheter is a device that consists of a fiberoptic bundle that emits light throughout its length and is